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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KAUSHAL, SUMESH

ART UNIT PAPER NUMBER

1636

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/605,042

Applicant(s)

WU ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) none is/are allowed.
- 6) ☐ Claim(s) none is/are rejected.
- 7) ☐ Claim(s) none is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicant's response filed on 10/16/01 has been acknowledged.

Claims 1-46 are pending.

► *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to an isolated DNA molecule comprising a kidney specific promoter operably linked to a heterologous DNA sequence containing a non-native apical surface membrane targeting sequence, classified in class 435, subclass 320.1 and 325.
- II. Claims 19-28, drawn to a transgenic non-human mammal and a method of producing a recombinant polypeptide using the non-human mammal, wherein the germ and somatic cells of the non-human mammal contain a recombinant construct comprising a kidney specific promoter operably linked to a heterologous DNA sequence containing a non-native apical surface membrane targeting sequence, classified in class 800, subclass 4 and 8.
- III. Claims 29-37, drawn to an isolated DNA molecule comprising a kidney specific promoter operably linked to a heterologous DNA sequence in which basolateral surface membrane targeting signals are inactivated or deleted, classified in class 435, subclass 320.1, 325.
- IV. Claims 38-46, drawn to a transgenic non-human mammal and a method of producing a recombinant polypeptide using the non-human mammal, wherein the germ and somatic cells of non-human mammal contain a recombinant construct

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comprising a kidney specific promoter operably linked to a heterologous DNA sequence in which basolateral surface membrane targeting signals are inactivated or deleted, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and II, IV are related as product and process of use respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated DNA constructs of Group I and III can also be used to make recombinant proteins in-vitro by transforming appropriate host cells. In addition the DNA constructs can also be used to produce the recombinant protein by administering the construct in-vivo using a viral or non-viral vectors. Thus these inventions are distinct and are of separate uses.

Inventions of Groups I and III are chemically, biologically and functionally distinct from each other and thus one does not render the other obvious. The DNA, vector and host cells of Group I are not required to produce the DNA, vector and host cells of Group III. The structure and mode of action of a genetic construct containing a non-native apical surface membrane targeting sequence is distinct from the construct containing a DNA molecule wherein the basolateral surface membrane targeting signals are inactivated or deleted. Therefore, the inventions of the two groups are capable of supporting separate patents.

Inventions of Groups II and IV are chemically, biologically and functionally distinct from each other and thus one does not render the other obvious. The transgenic non-human mammal of Group II encodes a non-native apical surface membrane targeting sequence which is distinct from the transgenic non-human mammal of Group IV encoding a DNA molecule wherein the basolateral surface membrane targeting signals are inactivated or deleted. Therefore, the inventions of the two groups are capable of supporting separate patents.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Zeta Adams, whose telephone number is (703) 305-3291.

S. Kaushal
Patent examiner


TERRY MCKELVEY
PRIMARY EXAMINER